REMARKS/ARGUMENTS

Claims 48, 49, 53, 55-58, 66, 67, 73, 74, and 76-81 are currently pending. Applicants have cancelled Claims 48, 49, 53, 55-58, 66, 67, 73, 74, and 76-81 and have cancelled previously withdrawn claims 51, 52, 59, 68-72 and 75. New Claims 82-87 have been added in order to expedite allowance of the application. The Applicants contend that no new matter has been added by these amendments.

Withdrawal of previous Objections and Rejections

The Examiner has withdrawn all of the previous objections and rejections.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 48, 49, 53, 55-58, 66, 67, 73, 74, and 76-81 under 35 U.S.C. § 112, first paragraph, as lacking enablement necessary for the skilled artisan to practice the invention commensurate in scope with the pending claims. The Examiner argues that while the claims are enabled for a method to select a cancer patient who is predicted to benefit from therapeutic administration of gefitinib comprising detecting the level of E-Cadherin polynucleotides in a sample of tumor cells from said patient, comparing said level to a level of E-Cadherin polynucleotides in a sample of tumor cells from a subject having the same type of cancer and that is resistant to gefitinib, and selecting the patient as being predicted to benefit from therapeutic administration of gefitinib if the level of E-Cadherin polynucleotides in the sample of tumor cells from said patient is higher than the level of E-Cadherin polynucleotides in the sample of tumor cells from the subject that is resistant to gefitinib, the claims are not enabled for methods to select a cancer patient, who is predicted to benefit from therapeutic administration of an EGFR inhibitor selected from the group consisting of gefitinib and erlotinib comprising (a) detecting in a sample of tumor cells from just any patient (including those without lung cancer), (b) comparing the level of expression of E-Cadherin polynucleotides with just any type of disorder or condition that has been correlated with sensitivity or resistance to the EGFR inhibitor or to selecting any type of patient with tumor cells expressing any amount of e-Cadherin polynucleotide.

Solely to expedite prosecution, Applicants have provided new claims accordingly to

overcome the Examiner's concerns. These new claims focus on lung cancer patients, therapeutic administration of the specific EGFR inhibitors gefitinib and erlotinib and comparison of the expression level of an E-Cadherin polynucleotide detected in cells from the cancer patient sample to a level of expression of the E-Cadherin polynucleotide that has been correlated in lung cancer cells with sensitivity and resistance to the specific EGFR inhibitors and selecting the lung cancer patient as being predicted to benefit from therapeutic administration of gefitinib or erlotinib if the expression level of the E-Cadherin polynucleotide in the patient's tumor cells is statistically more similar to the expression level of the E-Cadherin polynucleotide that has been correlated with sensitivity to gefitinib or erlotinib than to resistance to gefitinib or erlotinib. Support for gefitinib is found throughout the specification and support for erlotinib as an EGFR inhibitor is found on page 2, line 1 of the specification.

In addition, as discussed in the previous Office action response, the specific EGFR inhibitors gefitinib and erlotinib both share the same mechanism of action (i.e. act as ATP mimetics) that would thus enable one of skill in the art to predictably substitute one for the other to perform the claimed method.

New Claim 82 clearly defines that the patient to be tested is a lung cancer patient and that the method includes determining the level of expression of an E-Cadherin polynucleotide in a sample of lung cancer tumor cells from a lung cancer patient and therefore the claims would not include a patient without lung cancer. In addition, new Claim 82 clearly states that the level of expression of the E-Cadherin polynucleotide detected in the cells from the lung cancer patient sample is compared to a level of expression of the E-Cadherin polynucleotide that has been correlated in lung cancer cells with sensitivity or resistance to the specific EGFR inhibitors and therefore the correlation is not to just any disease or condition. Also, the expression level of the E-Cadherin polynucleotide in the lung cancer patient's tumor cells has to be statistically more similar to the expression level of the E-Cadherin polynucleotide that has been correlated with sensitivity to the specific EGFR inhibitors than to resistance to the specific EGFR inhibitors and thus not just any amount of expression of the E-Cadherin polynucleotide is used to predict the lung cancer patient that will benefit from therapeutic administration of the EGFR inhibitor.

In view of cancelling claims 1-81 and adding new claims 82-87, withdrawal of this rejection is respectfully requested. Applicants respectfully submit that given the guidance

provided in the specification (including Examples 1 and 2 in the Specification) and the level of knowledge in the art at the time of the present invention, one of ordinary skill in the art would be able to make and use the present invention as claimed without undue experimentation. Applicants therefore submit that the pending claims are sufficiently supported and enabled in the specification to meet the requirements of 35 U.S.C. § 112, first paragraph and that no undue experimentation would be required by one of skill in the art to perform the method of the presently claimed invention. Withdrawal of this rejection is respectfully requested.

Double Patenting

The Examiner has maintained the provisional rejection of Claims 48, 49, 53, 55-58, 66, 67, 73, 74, and 76-81 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Patent Application Serial No. 11/781,946. There are currently no claims from either the instant application or co-pending Application No. 11/781,946. Applicants will address this provisional rejection when allowable subject matter from these applications has been identified and requests that this rejection be held in abeyance until such time.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,
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